IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
WESTERN DIVISION

Michael Klein,

Plaintiff

v.

Central States, Southeast and Southwest Areas Health and Welfare Plan,

Defendant

Case No. 3:08CV02268

ORDER

This is a case in which Plaintiff Michael Klein claims medical treatment benefits under the Employee Retirement Income Security Act of 1974, 29 U.S.C. §§ 1001 et seq. [ERISA]. Klein alleges that the Trustees of the Central States, Southeast and Southwest Areas Health and Welfare Fund [Central States] acted arbitrarily and capriciously in concluding that a non-myeloablative allogeneic stem cell transplant for the treatment of chronic lymphocytic leukemia was experimental and therefore not covered under the Central States' plan.

Jurisdiction is proper under 28 U.S.C. § 1331. Pending are plaintiff's motion for judgment on the Administrative Record [Doc. 9] and defendant's cross-motion for judgment on the Administrative Record [Doc. 11]. For the following reasons, plaintiff's motion is granted and defendant's motion is denied.

Background

Plaintiff Michael Klein suffers from chronic lymphocytic leukemia [CLL]. He is a participant in the Central States, Southeast and Southwest Areas Health and Welfare Plan [Plan]. Klein's physician, Dr. Leslie Andritsos of the James Cancer Center, Ohio State University, recommends an allogeneic bone marrow transplant. Klein's brother is a perfect donor match. The Central States Health and Welfare Plan Document [Plan Document] governs Klein's claim.

Klein's doctors diagnosed him with CLL in 2005. Dr. Andritsos initially treated Klein with chemotherapies like Rituxan and Fludarabine, but Klein's condition responded only partially. Klein asked Medical Mutual of Ohio [Medical Mutual] to approve his participation in a clinical study for an experimental drug called GRN-163L. Medical Mutual approved the charges for this treatment on behalf of Central States.

Klein initially achieved an excellent result, but then his disease continued to progress. Dr. Andritsos recommended an allogeneic bone marrow transplant and requested a predetermination that Central States would cover the procedure. After consulting an independent medical expert, Medical Mutual concluded that the treatment was experimental and denied coverage. The independent reviewer's report is not included in the Administrative Record.

Dr. Andritsos appealed Medical Mutual's determination. Medical Mutual again consulted an independent medical expert and denied the appeal, stating that the treatment is experimental. The second independent reviewer's report is not included in the Administrative Record.

On October 9, 2007, Dr. Andritsos requested an additional review as mandated under Ohio law. This procedure was not required by the Plan Document, and the Ohio statutes under which the

review was conducted were likely pre-empted by ERISA. *See* 29 U.S.C. § 1144. However, Dr. Andritsos submitted to the appeal and answered the questions required by Ohio law.

Dr. Andritsos reported that Klein "is an otherwise exceedingly healthy 56-year old man" and that his disease was progressing "rapidly." [AR 137]. Dr. Andritsos stated that Klein had a high probability of death within two years on his current chemotherapy regimen. However, Dr. Andritsos stated, "recent studies analyzing reduced intensity conditioning regimens for allogeneic transplantation in CLL have shown a 54 to 75% overall survival with a 34 to 75% disease-free survival with the possibility of cure." [AR 137]. Dr. Andritsos also noted that Medical Mutual had previously approved the procedure for three other patients at James Cancer Hospital.

In accordance with Ohio law, Medical Mutual submitted Dr. Andritsos's request to three reviewers. Based on the criteria set forth in Ohio law, two of the three reviewers recommended that Medical Mutual deny treatment. Medical Mutual denied the appeal on October 23, 2007.

The Plan's Appeals Committee considered and denied Klein's appeal on November 21, 2007, stating that the treatment is considered experimental and investigational in nature, citing § 4.02 of the Plan.

Dr. Andritsos filed another appeal with the Plan on February 13, 2008. The appeal stated that "[n]o other therapeutic modality besides allogeneic transplantation has been shown to offer long-term disease control," and explained why Klein was a good candidate. [AR 010].

The Plan submitted the appeal to Dr. Howard Fingert, a physician reviewer. Dr. Fingert concluded that the procedure is "experimental" and "not medically necessary." [AR 011]. Counsel for the Plan also prepared a memorandum for the Trustees stating that they would not be acting arbitrarily and capriciously by denying the claim.

The Trustee Appellate Review Committee met on May 13, 2008, and the meeting minutes are in the Administrative Record. The Committee denied the appeal, citing § 4.02 of the Plan Document. [AR 001].

Having exhausted all administrative remedies, Klein now seeks an order from this court directing the Plan to approve and pay for the proposed treatment.

Standard of Review

I apply an arbitrary and capricious standard in reviewing the decision of the Central States' Trustees. The terms in the Plan Document determine the appropriate standard of review. *Marks v. Newcourt Credit Group, Inc.*, 342 F.3d 444, 457 (6th Cir 2003). The Sixth Circuit and other courts have concluded that the Central States Plan Document affords discretion to the Trustees, requiring an arbitrary and capricious standard of review. *See, e.g. Bowen v. Central States, Se. & Sw. Areas Health & Welfare Fund*, 1992 WL 92832, at *2-3 (6th Cir.)(unpublished disposition); *Exbom v. Central States, Se. & Sw. Areas Health & Welfare Fund*, 900 F.2d 1138, 1141-42 (7th Cir 1990); *Collins v. Central States, Se. & Sw. Areas Health & Welfare Fund*, 18 F.3d 556, 559 (8th Cir. 1994).

Plaintiffs argue that this court should afford less deference to the Trustees due to a conflict of interest that could cause them to deny claims to reduce health care costs. Even though the Trustees themselves do not benefit financially by denying claims because Central States is a non-profit trust, plaintiffs argue that the Trustees' responsibility to ensure that the Plan remains properly funded motivates the Trustees to keep the cost of care low.

The Sixth Circuit has rejected the argument that an alleged conflict of interest alters the arbitrary and capricious standard of review. *Kalish v. Liberty Mu. Liberty Life Assur. Co. of Boston,*

419 F.3d 501, 506 (6th Cir. 2005). Any possible conflict of interest "should be taken into account as a factor in determining whether [the Trustees'] decision was arbitrary and capricious." *Calvert v. Firstar Finance, Inc*, 409 F.3d 286, 292 (6th Cir. 2005). The standard of review, however, "remains unchanged and the conflict of interest is to be considered in *applying* that standard." *Id.* (emphasis in original).

Plaintiffs further argue that the defendant bears the burden of proof regarding plaintiffs' claim for benefits.

The text of the Plan places the burden of proving eligibility for benefits on the claimant:

> The burden of proof in demonstrating any fact essential to the approval of any claim for benefits, including eligibility for any claimed benefit and the extent to which a claimed benefit is covered or payable in accordance with this Plan, shall at all times be the responsibility of the claimant.

Plan Document, Art IX, § 9.06(b).

Plaintiff Klein, however, argues that common law trust principles require an ERISA-regulated plan administrator to prove exclusions from coverage.

Common law trust principles cannot negate the express terms of an ERISA plan. As the Sixth Circuit has held, "[a] primary purpose of ERISA is to ensure the integrity and primacy of the written plans. *Health Cost Controls v. Isbell*, 139 F.3d 1070, 1072 (6th Cir. 1997) (citations omitted). Although common law "fills the gaps of ERISA to assist in the interpretation of ERISA plans . . . federal courts may not apply common law theories to alter the express terms of written benefit plans." *Id.* Where the common law and the terms of the trust conflict, the terms of the trust instrument control. *Cobell v. Kempthorne*, 532 F. Supp. 2d 37, 101 (D.D.C. 2008).

The claimant's reliance on the court's opinion in *Caffery v. Unum Life Ins. Co*, 1997 WL 49128, *3 (6th Cir.), is misplaced. In *Caffery*, the court concluded that the administrator bore the

burden of proving an exclusion from coverage, citing "common law trust principles." *Id.* The plan at issue in *Caffery*, however, contained no express provision placing the burden on the claimant. *Id.* at *2.

In this case, the plaintiff must prove that he is eligible for benefits. Even if the common law of trusts would allocate the burden of truth differently, common law rules cannot alter the express provision of the Plan.

Discussion

I. Interpretation of Plan Provisions § 4.02 and § 4.17

Klein argues that the Trustees reviewed and denied coverage under the improper provision of the Plan Document. The Trustees based their denial on Article IV, § 4.02 of the Plan Document [Non-Standard Care Exclusion], which provides:

> 4.02 EXCLUSION OF PAYMENT FOR TREATMENT NOT CONSIDERED STANDARD MEDICAL CARE OR MEDICALLY NECESSARY.
>
> A Covered Individual shall not be entitled to payment of any charges for care, treatment, services or supplies which are not medically necessary or are not uniformly and professionally endorsed by the general medical community as Standard Medical Care, Treatment, Services or Supplies.

The Minutes of the Trustee Appellate Review Committee cite Article IV, § 4.02 as the basis for denial. [AR 001].

Klein argues that the Trustees should have considered his claim under Article IV, § 4.17 [Limitation on Transplants] of the Plan Document, which provides:

> 4.17 LIMITATION ON ELIGIBILITY FOR COVERAGE OF CERTAIN ORGAN OR TISSUE TRANSPLANTS
>
> Benefits for bone marrow … transplants, including all related services, are payable only if the recipient provides requested documentation for consideration by the Fund's Medical Consultants on a pre-admission basis. Such documentation will

include, but may not be limited to, written opinions by Physicians associated with the case testifying to the following:

(a) Absence of significant co-existing morbidity;

(b) Evidence of medical suitability of candidate for transplantation;

(c) Criteria for patient selection is in agreement with published medical literature;

(d) Alternative procedures, services or courses of treatment are not effective or available; and

(e) Facility and physicians involved in transplant services have appropriate approval by regulatory agencies and from internal authorities.

After consideration by the Fund's Medical Consultants, each case will be brought to the Trustees for their review. No organ or tissue transplant proposed for coverage under this Section will be payable unless there is prior approval by the Trustees following their consideration of the circumstances of each case. The Fund's financial responsibility for Hospital, medical and other expenses incident to, or resulting from, and transplant of any Covered Individual, including expenses incurred in any post-transplant treatment and in any complications arising from the transplant at any time, shall be limited to the following aggregate amounts:
…. ….

Bone Marrow-
Autologous [$] 200,000
Allogeneic Related [$] 300,000
Allogeneic Unrelated [$] 400,000

There is no inherent reason that, as the Trustees have concluded here, the Non-Standard Treatment Exclusion in § 4.02 cannot bar a treatment that the Limitation on Transplants in § 4.17 might otherwise allow. Neither § 4.02 nor § 4.17 expands a covered individuals' right to treatment. Section 4.02 states that a covered individual "shall not be entitled to payment" unless the conditions are met. Section 4.17 allows for transplant "only if" the documentation requirements were met. Further, § 4.17 states that, "No organ or tissue transplant proposed for coverage under this Section

will be payable unless there is prior approval by the Trustees following their consideration of the circumstances of each case."

Neither of these provisions suggests that § 4.17 makes a treatment payable that would be barred under another provision of the plan. The language "only if" – as opposed to simply "if" – indicates that § 4.17 limits rather than expands on rights established elsewhere in the document.

Further, the plaintiff argues that I must strictly construe ambiguous terms in the Plan Document against the drafter – the defendants. However, as described above, the terms of the Plan Document itself require that I afford deference to the Trustees' interpretation of the document. *See* *Bowen, supra*, 1992 WL 92832, at *2-3 (concluding that the Central States Plan Document affords discretion to Trustees to interpret terms). Where the Trustees have discretion to interpret the Plan Document, I may only disturb an unreasonable interpretation. *See* *Moos v. Square D. Co.*, 72 F.3d 39, 42 (6th Cir. 1995); *Hampton v. Dana Corp*, 2005 WL 2615997, at *1 (6th Cir. 2005). Trustees' interpretation of the Plan Document is not unreasonable.

I only consider, therefore, whether the Trustees properly denied Klein's claim under § 4.02.

II. Admissibility of Nelson Affidavit

Klein argues that the Trustees failed to provide a "full and fair" review of his claim as required by ERISA. 29 U.S.C. § 1133. First, Klein argues that the Trustees failed to provide their final reviewer, Dr. Fingert, with the complete Administrative Record. Klein notes that Dr. Fingert's report states that he received only Central States's "referral form and the submitted clinical highlights." [AR 011].

Second, Klein argues that the Trustees themselves failed to consider the entire Administrative Record, and instead reviewed only Dr. Fingert's report. In support, Klein cites a

passage from the Minutes of the Trustee's Meeting as evidence that the Trustees considered only Dr. Fingert's report. The Minutes state that "Dr. Fingert's entire report is attached for review" and provides a summary. [AR 005]. The Minutes do not discuss any other part of the Administrative Record. Klein argues that the only logical inference is that Dr. Fingert's report was the only part of the Administrative Record presented to the Trustees.

The Trustees, in response, proffer an affidavit by Albert E. Nelson, one of the Central States Trustees [Nelson Affidavit]. The Nelson affidavit states that Central States provided Dr. Fingert with "all of the information that Central States had pertaining to Mr. Klein's claim." [Nelson Aff. ¶ 17]. Further, the Affidavit states that the Trustees reviewed the entire Administrative Record in considering and denying Klein's appeal. [Nelson Aff. ¶ 18]**.**

The first question is whether this affidavit is admissible. The Sixth Circuit has held that a "district court may consider evidence outside of the administrative record only if that evidence is offered in support of a procedural challenge to the administrator's decision." *Wilkins v. Baptist Healthcare System, Inc.*, 150 F.3d 609, 619 (6th Cir. 1998). A district court may consider such extrinsic evidence where the claimant asserts an "alleged lack of due process afforded by the administrator." *Id.* Klein's claim is precisely the type contemplated by the court in *Wilkins.* The Nelson affidavit, therefore, is admissible to shed light on whether the Trustees and their final reviewer considered the entire record.

Because Nelson is one of the Trustees, he has direct knowledge of what materials the Trustees reviewed. His affidavit is evidence, therefore, that the Trustees did review the entire Administrative Record in evaluating Klein's claim.

Nelson, however, has no direct knowledge of what materials Dr. Fingert actually reviewed, even if we assume he received the entire Administrative Record. Because the Nelson Affidavit provides no evidence to the contrary, I accept Dr. Fingert's own statement that he reviewed only the referral form and clinical highlights, not the entire Administrative Record.

III. Whether the Trustees' Ruling is Arbitrary and Capricious

Klein argues that the Trustees arbitrarily and capriciously denied him treatment under § 4.02 of the Plan. First, Klein argues that the Administrative Record does not support the Trustees' conclusion. Second, Klein argues that the Trustees' conflict of interest renders their decision arbitrary and capricious.

A. Adequacy of the Administrative Record

The Trustees denied Klein's claim under § 4.02 of the Plan Document. The defendants cite the following evidence from the Administrative Record in support of their conclusion that allogeneic stem cell transplantation is experimental for patients with Klein's form of leukemia: 1) Dr. Fingert's report [AR 011-015]; 2) statements of Dr. Leslie A. Andritsos, Mr. Klein's treating physician on February 13, 2008 [AR 007]; 3) statements of reviewing physicians in the Medical Mutual of Ohio Case Report, October 15, 2007 [AR 123-136]; and 4) statements in correspondence from Medical Mutual to Dr. Andritsos, dated August 31, 2007 and September 17, 2007 [AR 141-142]. The Administrative Record also contains various medical journal articles [AR 22-121]. I consider each in turn.

1. Dr. Fingert's Report

Dr. Fingert, the Trustees' final reviewer, concluded that the proposed treatment is "not medically necessary. It is experimental." [AR 011]. Plaintiffs, however, argue that Dr. Fingert's

report is worthless because he reviewed only the "referral form and clinical highlights," not Klein's complete file. [AR 011].

An ERISA plan administrator acts arbitrarily and capriciously by relying on an expert report based on a "cherry-picked" medical file. *Spangler v. Lockheed Martin Energy Systems, Inc.*, 313 F.3d 356, 362 (6th Cir. 2002). In *Spangler*, a vocational consultant concluded that the plaintiff could perform sedentary work. *Id.* The consultant's conclusion, however, did not examine the plaintiff himself and received only part of the plaintiffs' file for review. *Id.* The court concluded that the plan administrator had "cherry-picked" the plaintiff's file and concluded that the administrator's conclusion was arbitrary and capricious.

In this case, the referral form and clinical highlights appear nowhere in the Administrative Record. Neither this court nor the Trustees can know precisely what Dr. Fingert reviewed prior to making his decision. Because Dr. Fingert based his conclusions on incomplete evidence, like the consultant in *Spangler*, reliance on his report is arbitrary and capricious.

2. Statements of Dr. Leslie A. Andritsos

Defendants argue that even Dr. Andritsos, plaintiff's treating physician, stated that allogeneic stem cell transplants are experimental.

On February 13, 2008, Dr. Andritsos wrote: "At this point, because of [Mr. Klein's] clinically aggressive disease, poor initial response to fludarabine-based therapy, and rapid relapse (<12 months) *after completion of therapy, as well as progressive disease requiring salvage therapy with experimental therapeutics*, an allogenic stem cell transplant was recommended to the patient." [AR 007] [Emphasis supplied].

Contrary to the defendants' contention, this letter does not state that the proposed treatment is experimental. The plain, grammatically correct reading is that after having unsuccessfully treated Mr. Klein with "salvage therapy with experimental therapeutics," Dr. Andritsos is recommending an allogeneic stem cell transplant. The fact that the already-completed salvage therapy may be experimental simply does not suggest that the proposed transplant is.

Moreover, the defendant ignores Dr. Andritsos's statement elsewhere that "reduced intensity conditioning regimens for allogenic transplantation in CLL have shown a 54 to 75% overall survival with a 34 to 75% disease-free survival with possibility of cure" and that the transplant is "far superior to any commercially available chemotherapy-based regimen." [AR 137].

Dr. Andritsos's statements provide no support for the defendant's denial of treatment. It was arbitrary for the defendants to read the letter as stating that the proposed treatment is experimental.

3. Statements of Reviewing Physicians in Medical Mutual Case Report

Central States relies on a three-doctor review of Klein's claim conducted by Medical Mutual in October 2007 in compliance with Ohio state law. Plaintiff argues that this document is irrelevant because the reviewers were not asked whether the treatment was experimental within the meaning of the ERISA plan document.

Medical Mutual asked reviewers to address four elements specifically required by Ohio state law: 1) "[a] description of the patient's condition"; 2) whether the transplant is "more likely than not to be more beneficial to the client than standard treatments or procedures;" 3) an analysis of relevant medical and scientific literature; and 4) "the patient's suitability to receive the recommended or requested procedure according to a treatment protocol in a clinical trial, if applicable." [AR 124].

Reviewers received instructions to consider Klein's case file, current scientific literature, and "safety, efficacy, appropriateness and cost effectiveness." [AR 123-124].

Medical Mutual reviewers were not provided with the text of § 4.02 of the Plan, which bars payment for treatments that are "not medically necessary or are not uniformly and professionally endorsed by the general medical community as Standard Medical Care . . ." Indeed, the instructions Medical Mutual provided to its reviewers depart from § 4.02 in three important ways.

First, Medical Mutual instructed reviewers to consider "cost effectiveness," which is not part of § 4.02. Second, Medical Mutual instructed reviewers to consider whether the proposed treatment is "more likely than not to be more beneficial" than an alternative treatment. Section 4.02, in contrast, affords more deference to a plaintiff's treating physician – it does not require reviewers to second-guess the treating physician unless her recommendation is "not medically necessary" or inconsistent with professional consensus. Third, § 4.02 provides some guidance as to the meaning of "Standard Medical Care" – it must be "uniformly and professionally endorsed by the general medical community" as standard. Medical Mutual's reviewers, in contrast, received no guidance whatsoever as to the meaning of "standard."

The first reviewer recommended that Klein receive the treatment, stating: "There is sufficient evidence that the recommended treatment is more likely than not to prove beneficial . . . Allogeneic [Stem Cell Transplant] remains the only curable modality of treatment for [Klein's condition]." [AR 125].

The second reviewer concluded: "There is insufficient evidence to demonstrate that the recommended or requested treatment or procedure is more likely than not to be more beneficial to the client than standard treatment or procedures." [AR 128]. As part of his rationale, the second

reviewer stated that "[b]one marrow and peripheral stem cell transplantations are under clinical observation." [AR 129]. Further, he noted that "[g]iven the toxicity of allo-SCT, this procedure should be restricted to eligible patients who can expect a significant reduction in life expectancy under alternative therapies." [AR 129].

The reviewer's conclusion was not based on the fact that the proposed treatment was "experimental," but rather that Klein's condition was insufficiently dire to justify the risks associated with the transplant. The reviewer explained that despite Klein's only "partial response" to various chemotherapies, "it is not clear at all in the literature or otherwise, whether he would benefit more from an allogeneic stem cell transplant or continuation of observation or standard chemotherapy program for his stage of disease." [AR 131].

The third reviewer likewise concluded that there is "insufficient evidence that the requested treatment is more likely than not to be more beneficial than standard treatments." [AR 133]. This reviewer stated, without elaboration, that "reduced intensity conditioning allogeneic stem cell transplant is experimental/investigational for this condition at this time." [AR 133].

Defendants' assertion that two of the three reviewers support defendants' conclusion that the treatment was experimental in nature and therefore excluded by § 4.02 is dubious at best. The experts were not asked to determine whether the procedure was excluded by the language of § 4.02. They were not even directly asked whether the procedure was experimental, standard, or medically necessary. The reviewers were asked to consider whether other treatments were superior to that proposed by the treating physician.

Moreover, the explicit instruction regarding cost-effectiveness casts a shadow over the reviewers' conclusions regarding § 4.02. The is issue is whether the treatment is experimental, not whether its prospective benefits outweigh its costs.

The third reviewer's conclusory statement that the treatment is experimental provides support for defendants' position, even if it was not in response to the appropriate question. However, the second reviewers' recommendation provides no support to the defendants. The note that the treatment is under "clinical observation" is ambiguous and peripheral to the reviewer's conclusion. Moreover, the second reviewer indicates that the proposed treatment is appropriate for certain patients with Klein's condition. Thus, the Medical Mutual report contains a single, conclusory statement in support of the defendants' conclusion, and even this is potentially tainted by the fact that the third reviewer was not asked a properly framed question.

4. Correspondence From Medical Mutual to Dr. Andritsos

Medical Mutual cites two excerpts from letters Medical Mutual sent to Dr. Andritsos as evidence that the proposed treatment is experimental. [AR 142, 141]. Plaintiffs argue that these excerpts merely state Medical Mutual's conclusion that the proposed treatment is experimental. The defendants argue the excerpts from the letters are direct quotations from the expert opinions on which Medical Mutual relied in concluding that the treatments are experimental.

The first excerpt is from an August 31, 2007, letter from Medical Mutual to Dr. Andritsos: "The consensus opinion of medical experts in the field is that further clinical studies are needed to better define the safety and efficacy of reduced-intensity allogeneic transplants in the treatment of CLL. The proposed treatment is the subject of ongoing phase II clinical trials." [AR 142]. The second excerpt is from a September 17, 2007, letter from Medical Mutual to Dr. Andritsos: "While

reduced intensity transplantation has shown some evidence of efficacy, the long-term benefits of this treatment are not known. Furthermore, there is no available comparative study that clearly documents the superiority of this treatment over standard chemotherapy." [AR 141].

Defendant's claim that these letters restate direct quotations from independent experts is untenable. Neither letter attributes these conclusory statements to any particular expert. Moreover, both letters mention review by an independent physician, Medical Mutual's Chief Medical Officer, and a "comprehensive review process." [AR 141, 142]. Clearly, the quoted passages describe Medical Mutual's ultimate rationale for denying the treatment. They are not direct quotations from the opinion of an independent physician, and cannot be treated as evidence in support of defendant's conclusion.

5. Medical Journal Articles and Texts

The Administrative Record contains ten medical journal articles, abstracts and other texts discussing the proposed treatment. [1] The parties do not discuss the content of these articles, nor are they mentioned in the Trustee Appellate Review Committee minutes.

I have read the articles. Though admittedly not medically trained, I conclude – and I think as a layman, I fairly can do so on reading these articles – that none clearly indicates that the proposed allogeneic stem cell treatment is experimental for CLL. Indeed, most recommend this treatment in at least certain CLL cases.

Several articles indicate that allogeneic stem cell transplants hold positive results for CLL patients. A 2006 article states that allogeneic stem cell transplant is "[t]he only curative therapy for patients with CLL" [AR 022], and proposes "allogeneic stem cell transplantation for patients who

[1] Two articles focus on salvage regimens rather than transplants. [AR 043-059].

have failed Fludarabine-based chemotherapy or autologous transplantation and have a good performance status, no associated medical conditions precluding the procedure, an HLA-identical sibling or unrelated donor." [AR 022].

The abstract of a 2007 study evaluating the effects of allogeneic cell transplantation in CLL patients indicates that 70% of patients in the study exhibited disease response and 55% were in complete remission. [AR 070]. A 2006 report concludes that "allogeneic HCT [hematopoietic cell transplantation] after non-myeloablative conditioning might prolong median survival for patients with advanced CLL." [AR 071]. Another 2007 article indicates that "allogeneic stem cell transplantation has been used increasingly to treat patients with" CLL. [AR 090].

A 2007 article from *Leukemia* reports the consensus of an "international expert panel" on the use of allogeneic stem cell transplantation for CLL. The abstract states: "[k]ey elements of the consensus are (1) [allogeneic stem cell transplantation] is a procedure with evidence-based efficacy in poor-risk CLL; (2) although definition of 'poor-risk CLL' requires further investigation, [allogeneic stem cell transplantation] is a reasonable treatment option for younger patients" sharing certain enumerated characteristics. [AR 082]. Regarding the clinical success rate of allogeneic stem cell transplantation in CLL, the report stated, "[i]n summary, long-term disease-free survival and possibly cure seem to be possible in one-third to two-thirds of patients undergoing [allogeneic stem cell transplantation] for poor-risk CLL." [AR 084].

The results of a 1996 study indicate that researchers have known for over a decade [*i.e.*, as of the date of denial – for more than *twenty* years] that allogeneic transplants showed promising results in patients younger than sixty years of age. Of the fifty-four CLL patients in the study, 70%

achieved meatologic remission; and the three-year survival probability for all participants was 46%. [AR 060].

A 2004 article concludes that allogeneic stem cell transplant is a "valid option when aiming at cure for high risk CLL."[AR 108]. The article indicates that five years earlier, "allogeneic stem cell transplantation [was] increasingly considered in the management of medically fit patients with active CLL." [AR 107].

A 2004 review indicated that allogeneic stem cell transplantation is "the only curative approach" to CLL, "producing an extended disease-free survival in 25-60%" of patients. [AR 092]. Although the review indicated that research would focus on improving the treatment, the authors concluded that nonmyeloablative allogeneic stem cell transplantation "should be the treatment of choice for patients who have failed conventional chemo-antibody treatment." [AR 098].

Two of the articles qualify their support for the proposed treatment in CLL patients. A 2007 abstract concludes that "[a]llogeneic HCT has the potential to induce long-term disease-free survival in selected patients with advanced" CLL but that the use of transplants earlier in the course of CLL should be studied further. [AR 089]. A 2007 article provides the most support to the view that the proposed treatment is under investigation. While noting that the transplant can "deliver impressive remissions, clinical and molecular, in a significant number of patients," the authors note that "remissions are not long lasting, and relapses anticipated." [AR 039-040]. "Allogeneic HOT," the article continues, "has the ability to cure patients with CLL at the expense of an increased risk of morbidity and mortality." [AR 039]. The authors suggest that the "best timing" for the treatment "remains to be determined even in patients with high-risk features." [AR 040]. The authors recommend further clinical trials. [AR 040].

In sum, the vast majority of articles and texts in the record indicate that researchers have been aware of the beneficial effects of the proposed treatment in CLL patients for upwards of twenty years. Although certain questions about the proper application of the treatment may remain the subject of ongoing research, that fact does not support a conclusion that the treatment is "experimental."

6. Conclusion Regarding Adequacy of Evidence

The Administrative Record contains only two unambiguous statements in favor of the claim that the treatment is experimental: 1) a conclusory statement by Medical Mutual's third reviewer in the October 2007 report; and 2) the conclusion of Dr. Fingert, who, as described above, reviewed only the defendant's "referral form and the submitted clinical highlights" prior to making his conclusion. The weak evidentiary support for defendants' conclusion supports the conclusion that denying Klein treatment was arbitrary and capricious.

B. Alleged Conflict of Interest

As noted, the putative conflict of interest on the part of the trustees does not disqualify them from denying Klein's claim. But such possible conflict is a factor to be weighed in considering whether, in this instance, they acted arbitrarily and capriciously. A demonstrated conflict of interest may provide evidence that the plan administrator's ruling is arbitrary and capricious. *Calvert v. Firstar Finance, Inc*, 409 F.3d 286, 292 (6th Cir. 2005).

The record contains a letter from attorney Charles H. Lee of the defendant's law department in which he recommends that the defendant deny Klein's request for treatment. The letter briefly discusses data about the proposed treatment and then concludes: "While Mr. Klein's physician has recommended the Procedure, there are conflicting opinions from other independent medical experts.

Accordingly, I do not believe it would be arbitrary and capricious for the Fund's Trustees to deny Mr. Klein's request . . ." [AR 017].

Whether a decision would later be viewed as arbitrary and capricious should not be a part of the Trustees' consideration. This is the legal standard for judicial review of the medical decision. The Plan Administrator may only deny a claim on the basis of terms set forth in the Plan Documents. If the Trustees considered a standard other than that set forth in the Plan Documents, they acted arbitrarily.

To be sure there is no further evidence that the Trustees considered whether their decision could survive review under the arbitrary and capricious standard. But that their lawyer told them it could interjected an extraneous consideration into their own review. Even if such consideration does not constitute a conflict of interest, it potentially distracted the trustees from doing their job as faithfully as they should.

IV. Remedy

In light of the foregoing analysis, I conclude that the rejection of Klein's request for approval for a transplant was arbitrary and capricious. There is simply insufficient evidence to support the finding that the treatment was experimental under § 4.02. It is, moreover, apparent that the trustees misread – for whatever reason – the reference to experimental treatment in his doctor's letter. Doing so enabled them – most improperly and inaccurately – to point to her statements as supporting their decision. Those statements don't support their position, and it was arbitrary and capricious for the trustees to conclude and then assert that they did.

It is also possible that the trustees' deliberations were affected by considerations of cost-effectiveness, as referenced in the materials relating to Medical Mutual's review, and whether their decision, in the view of their attorney, could survive review.

In the event he prevails, as he has, the plaintiff asks for an order awarding benefits.

ERISA confers upon federal courts a range of remedial powers:

> A civil action may be brought ... by a participant, beneficiary, or fiduciary (A) to enjoin any act or practice which violates any provision of this subchapter or the terms of the plan, or (B) to obtain other appropriate equitable relief (i) to redress such violations or (ii) to enforce any provisions of this subchapter or the terms of the plan.

29 U.S.C. § 1132(a); *see also* *Cooper v. Life Insurance Co. of North America*, 486 F.3d 157, 171 (6th Cir. 2007).

Ordinarily, remand is the appropriate remedy where the plan administrator's decision-making process was flawed. *Moore v. Lafayette Life Ins. Co.*, 458 F.3d 416, 436 (6th Cir. 2006).

In extraordinary cases, however, district courts may award benefits. In *Glista v. Unum Life Ins. Co. of America*, 378 F.3d 113, 130 (1st Cir. 2004), the court ordered benefits, noting, among other factors, that the claimant's "medical condition call[ed] for resolving [the] controversy quickly. In *Bard v. Boston Shipping Ass'n*, 471 F.3d 229, 246 (1st Cir. 2006), the court concluded remand was inappropriate because "the remaining evidence compels the conclusion that [the claimant] is entitled to benefits" and because the plan administrator had prejudiced the claimant through delay. *Cf.* *Sullivan v. Cap Gemini Ernst & Young U.S.*, 518 F. Supp. 2d 983, 999 (N.D. Ohio 2007) (distinguishing *Glista* and *Bard*, but only because the plan administrator's defense was based on claimant's signing of a "contractual release, not on an interpretation of the plan language or the facts surrounding [the claimant's] disability").

Time is of the essence in this case. Klein's medical situation is critical, and his condition is deteriorating rapidly. Further, the Administrative Record supports Dr. Andritsos's conclusion that the allogeneic stem cell transplant is the only treatment to which Klein's condition is likely to respond. The Plan's convoluted review process – which included a detour for apparently extraneous review under Ohio law – and the Trustee's referral to a reviewing physician with inadequate information have delayed Klein's treatment long enough.

An award of benefits is entirely appropriate in this extraordinary case.

Conclusion

For the forgoing reasons, it is hereby:

ORDERED THAT:

1. Plaintiff's motion for judgment on the Administrative Record [Doc. 9] be, and the same hereby is granted;

2. Defendant's motion for judgment on the Administrative Record [Doc. 11] be, and the same hereby is denied; and

3. The defendants shall immediately award the benefits which plaintiffs seeks, and to which he is entitled.

So ordered.

s/James G. Carr
James G. Carr
Chief Judge